

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ROME DIVISION

UNITED STATES OF AMERICA

PLAINTIFF,

v.

CHARLES C. ADAMS, M.D.,
CHARLES C. ADAMS, M.D., P.C.,
D/B/A FULL CIRCLE MEDICAL
CENTER, AND PERSONAL
INTEGRATIVE MEDICINE

DEFENDANTS.

Civil Action No.

No. 4:18-cv-191-HLM

PLAINTIFF'S INITIAL DISCLOSURES

Plaintiff the United States of America, by and through the United States Attorney for the Northern District of Georgia, hereby makes the following initial disclosures in accordance with Federal Rule of Civil Procedure Rule 26(a)(1) and Local Rule 26.1.

(1) State precisely the classification of the cause of action being filed, a brief factual outline of the case including plaintiff's contentions as to what defendant did or failed to do, and a succinct statement of the legal issues in the case.

In this action, the United States seeks to recover damages, civil penalties and other relief in connection with claims under the False Claims Act, 31 U.S.C. §§ 3729 *et. seq.*, as well as the common-law doctrines of payment by mistake and unjust enrichment. Between November 2008 and September 2015, Defendants submitted approximately 4500 claims for chelation therapy that Dr. Adams administered to patients using the drug calcium disodium versentate, or edetate calcium disodium (EDTA), which the FDA has only approved as a treatment for lead poisoning and lead encephalopathy.

Medicare only covers EDTA when used to treat lead poisoning and lead encephalopathy, which are diagnosed on the basis of acute exposure to lead and a blood test that reveals significant amounts of lead in a patient's body – *e.g.* BLLs in excess of 50/80 mcg.¹ Additionally, Medicare does not cover EDTA when used as an “alternative” or “experimental” therapy. In connection with the approximately 4500 claims that Defendants submitted between 2008 and 2015, Defendants received approximately \$1.5 million in reimbursements from Medicare.

¹ 50 mcg is a threshold BLL for a symptomatic patient, while 80 mcg is a threshold for an asymptomatic patient.

Defendants' EDTA chelation claims were "false" within the meaning of the FCA. First of all, the claims falsely stated - through the use of ICD-9 Diagnostic Codes associated with various forms of HMP (*e.g.*, lead poisoning) - that patients were chelated to treat HMP/lead poisoning, when in truth (as admitted by Dr. Adams), Defendants do not treat HMP/lead poisoning, but other generalized conditions. Second, the claims were false as they sought reimbursement for EDTA chelation that was administered as "alternative" or "experimental" treatments for conditions such as poor circulation, heart disease and premature aging, which are deemed non-reimbursable under Medicare rules and National Coverage Determination 20.22. Finally, the claims were false in that they sought reimbursement for EDTA chelation therapy that was not medically necessary.

Defendants tendered these false claims to the Government with "knowledge" - as that term is defined by the FCA - of their falsity. Specifically, in submitting the claims, Defendants either had actual knowledge of, or acted in deliberate ignorance or reckless disregard of, the falsity of the claims.

The legal issues in the matter include, but are not necessarily limited to, the following:

1. Whether Defendants' claims were "false" within the meaning of the FCA?

2. Whether the falsity associated with Defendants' claims was "material" within the meaning of the FCA?
3. Whether Defendants' submitted their claims with FCA "knowledge" of the falsity of such claims.
4. Whether the United States is able to recover the approximately \$1.5 million in reimbursements that it provided to Defendants under the doctrine of payment by mistake?
5. Whether the United States is able to recover the approximately \$1.5 million in reimbursements that it provided to Defendants under the doctrine of unjust enrichment?

(2) Describe in detail all statutes, codes, regulations, legal principles, standards and customs or usages, and illustrative case law which plaintiff contends are applicable to this action.

1. The False Claims Act (FCA), 31 U.S.C. §§ 3729, *et seq.* provides in pertinent part that any person who:

- knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
- knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . .

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . , plus 3 times the amount of damages which the Government sustains because of the act of that person. 31 U.S.C. § 3729(a)(1). *See also* 28 C.F.R. § 85.3(a)(9). The FCA was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (“FERA”), enacted May 20, 2009. Section 3729(a)(1) of the prior statute applies to conduct that occurred before FERA was enacted, and Section 3729(a)(1)(A) of the revised statute applies to conduct after FERA was enacted. Section 3729(a)(1)(B) is applicable to all claims in this case by virtue of Section 4(f) of FERA.

For violations occurring prior to May 20, 2009, the False Claims Act provided in pertinent part that a person is liable to the United States government for each instance in which the person “knowingly presents, or causes to be presented, to an officer or employee of the United States government . . . [a] false or fraudulent claim for payment or approval.” 31 U.S.C. § 3729(a)(1) (1986).

As amended in 2009, the False Claims Act extends liability, both before and after its amendments, to any person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” 31 U.S.C. § 3729(a)(1)(B) (2009).

The False Claims Act defines the terms “knowing” and “knowingly” to mean that a person, with respect to information: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b) (1986); 31 U.S.C. § 3729(b)(1)(A) (2009). The False Claims Act further provides that no proof of specific intent to defraud is required. 31 U.S.C. § 3729(b) (1986); 31 U.S.C. § 3729(b)(1)(B) (2009).

2. Pursuant to 42 U.S.C. § 1395y(a)(1)(A), Medicare only covers items and services that are “reasonable and necessary for the diagnosis or treatment of illness or injury.” Items and services that are not reasonable and necessary are excluded from coverage under Medicare.

3. CMS Medicare Program Integrity Manual, Chapter 3, Section 3.6.2.2, states that items are “reasonable and necessary” and thus covered by Medicare if, *inter alia*, they are “not experimental or investigational.”

4. National Coverage Determination (NCD) 20.22 provides that, “the use of EDTA as a chelating agent to treat atherosclerosis, arteriosclerosis, calcinosis, or similar generalized conditions not listed by the FDA as an approved use is not covered. Any such use of EDTA is considered experimental.

5. The “payment by mistake” doctrine enables the United States to recover payments made under a material and erroneous belief that the payments were properly owed. *See U.S. v. Medica-Rents Co.*, 285 F.Supp.2d 742, 776 (N.D. Tex. 2003).

6. Under the doctrine of “unjust enrichment,” “a person is unjustly enriched if the retention of a benefit would be unjust[.]” and the United States can recover where: (1) it has a reasonable expectation of repayment, (2) the recipient of the payment should expect to repay, and (3) society’s expectations would be defeated by non-payment. *U.S. v. Rogan*, 459 F.Supp.2d 692, 728 (N.D. Ill. 2006).

Illustrative cases include, but are not limited to, the following:

- *U.S. ex rel. Ryan v. Lederman*, No. 04-CV-2483, 2014 WL 1910096, (E.D.N.Y. May 13, 2014)
- *U.S. ex rel. Youn v. Sklar*, 273 F. Supp.3d 889 (ND. IL. 2017)
- *U.S. v. Mount Sinai Hospital*, 256 F.Supp.3d 443 (S.D.N.Y, 2017)
- *U.S. ex rel. Polukoff v. St. Mark’s Hosp.*, 895 F.3d 730 (10th Cir. 2018)
- *U.S. v. Paulus*, 894 F.3d 267 (6th Cir. 2018)
- *U.S. ex rel. Matheny v. Medco Sols., Inc.*, 671 F.3d 1217 (11th Cir. 2012)
- *U.S. v. Sci. Applications Int’l Corp.*, 626 F.3d 1257 (D.C. Cir. 2010)

- *U.S. ex rel. Gelbman v. City of New York*, No. 14-CV-771 (VSB), 2018 WL 4761575 (S.D.N.Y. Sept. 30, 2018)
- *U.S. v. Crumb*, No. 15-0655-WS-N, 2016 WL 4480690 (S.D. Ala. Aug. 24, 2016)
- *U.S. v. Kinetic Concepts, Inc.*, No. CV 08-01885-BRO, 2017 WL 2713730 (C.D. Cal. Mar. 6, 2017)
- *U.S. ex rel. Brown v. Celgene Corp*, No. CV 10-3165-GHK, 2014 WL 3605896, (C.D. Cal. July 10, 2014)
- *U.S. ex rel. Bibby v. Wells Fargo Bank, N.A.*, 906 F. Supp.2d 1288 (N.D. Ga. 2012)
- *U.S. v. Mackby*, 261 F.3d 821 (9th Cir. 2001)
- *U.S. v. Medica-Rents Co.*, 285 F.Supp.2d 742 (N.D. Tex. 2003)
- *U.S. v. Rogan*, 459 F.Supp.2d 692 (N.D. Ill. 2006)

(3) Provide the name and, if known, the address and telephone number of each individual likely to have discoverable information that you may use to support your claims or defenses, unless solely for impeachment, identifying the subjects of the information. (Attach witness list to Initial Disclosures as Attachment A.)

(4) Provide the name of any person who may be used at trial to present evidence under Rules 702, 703, or 705 of the Federal Rules of Evidence. For all

experts described in Fed.R.Civ.P. 26(a)(2)(B), provide a separate written report satisfying the provisions of that rule. (Attach expert witness list and written reports to Responses to Initial Disclosures as Attachment B.)

- To date, Plaintiff has not identified any experts that it intends to use at trial. Plaintiff will update this this disclosure in accordance with the Federal Rules of Civil Procedure, the Local Rules and other applicable orders of the Court.

(5) Provide a copy of, or a description by category and location of, all documents, data compilations or other electronically stored information, and tangible things in your possession, custody, or control that you may use to support your claims or defenses unless solely for impeachment, identifying the subjects of the information. (Attach document list and descriptions to Initial Disclosures as Attachment C.)

(6) In the space provided below, provide a computation of any category of damages claimed by you. In addition, include a copy of, or describe by category and location of, the documents or other evidentiary material, not privileged or protected from disclosure, on which such computation is based, including materials bearing on the nature and extent of injuries suffered, making such documents or evidentiary material available for inspection and copying (Rev.

03/01/11) APP.B - 4 as under Fed.R.Civ.P. 34. (Attach any copies and descriptions to Initial Disclosures as Attachment D.)

- As noted in the Complaint, Plaintiff alleges seeks to recover approximately \$1.5 million, in addition to FCA damages and penalties. Currently, Plaintiff does not have any non-privileged damages computation. Plaintiff will update this this disclosure in accordance with the Federal Rules of Civil Procedure, the Local Rules and other applicable orders of the Court.

(7) Attach for inspection and copying as under Fed.R.Civ.P. 34 any insurance agreement under which any person carrying on an insurance business may be liable to satisfy part or all of a judgment which may be entered in this action or to indemnify or reimburse for payments made to satisfy the judgment. (Attach copy of insurance agreement to Initial Disclosures as Attachment E.)

- *Not applicable*

(8) Disclose the full name, address, and telephone number of all persons or legal entities who have a subrogation interest in the cause of action set forth in plaintiffs cause of action and state the basis and extent of such interest.

- *Not applicable*

This 22nd day of April, 2019.

Respectfully submitted,

BYUNG J. PAK
UNITED STATES ATTORNEY

/s/ Paris A. Wynn
PARIS A. WYNN
ASSISTANT U.S. ATTORNEY
U.S. Attorney's Office
Richard B. Russell Building
75 Ted Turner Drive
Atlanta, Georgia 30303
(404) 581-6302
(404) 581-6181 (facsimile)
Ga. Bar No. 933549
paris.wynn@usdoj.gov

Attachment A

1. Defendant Dr. Charles C. Adams - Dr. Adams is likely to have information concerning Defendants' administration of chelation therapy, as well as Defendants' billing practices for such therapy. Additionally, Dr. Adams will have information pertaining to chelation, EDTA, alternative medicine and integrative medicine.

2. Current/Former Employees of Defendants - Current and former employees of Defendants will have information pertaining to Defendants' administration and/or knowledge of chelation, EDTA, alternative medicine and integrative medicine.
 - a. Upon information and belief, Defendants are currently aware of the names, addresses and other contact information associated with their current and/or former employees.

 - b. Plaintiff will obtain the names, addresses and other contact information associated with Defendants' current and former employees as discovery progresses.

Plaintiff reserves the right to update this disclosure to the extent that additional witnesses or identified through discovery or otherwise.

Attachment C

1. Patient Medical Records: Plaintiff intends to utilize the medical records associated with patients to whom Defendants administered, *inter alia*, chelation therapy. Upon information and belief, these medical records are currently in the possession of Defendants.
2. Documents Reflecting Defendants' Advertisements/Public Statements Regarding Chelation: Plaintiff intends to utilize Defendants' public statements regarding chelation therapy and alternative and/or integrative medicine - *i.e.*, statements on their internet webpage(s), and material contributed to the webpages of entities associated with alternative and/or integrative medicine. Upon information and belief, these statements and/or documents are already in the possession of Defendants.

Plaintiff reserves the right to supplement this list should additional responsive material be identified during the discovery period.

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CERTIFICATE OF SERVICE

I certify that I electronically filed the within and foregoing document with the Clerk of Court using the CM/ECF system, which will automatically send email notification to the following attorney of record:

Lauren A. Warner, Esq.
Chilivis, Cochran Larkins & Bever LLP

This 22nd day of April, 2019.

/s/ Paris A. Wynn
PARIS A. WYNN
Assistant United States Attorney